FEB 1 4 2001

510(k) SUMMARY
July 17, 2000
SYNTRA™ DIALYZER
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K002210

Submitter's Name:	Ann Marie Pahlman
Address:	1620 Waukegan Rd., MPGR-A2E McGaw Park, IL 60085
Phone:	847-473-6078
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Contact:	Ann Marie Pahlman or Robert L. Wilkinson
Date Prepared:	July 17, 2000
Trade Name:	SYNTRA™ Dialyzer
Common Name:	Dialyzer
Classification Name:	High Permeability Hemodialysis System per 21 CFR 876.5860
Equivalent predicate:	PSN™ Polysynthane Dialyzer Cobe Centrysystem 14 PES Cobe Arylane-H Dialyzer Gambro Polyflux-S Dialyzer Gambro HC 14R Hemoconcentrator Fresenius Hemoflow Dialyzer
Device Description:	Model 120 and Model 160 Dialyzers
Intended Use:	Hemodialysis with SYNTRA™ is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.
Summary of the Technological Predicate Device:	The general function and materials of the subject SYNTRA™ Dialyzers are the same as the Baxter PSN™ Dialyzers cleared under K980656 & K980658, the Cobe Centrysystem 14 PES Dialyzer cleared under K955592, the Cobe Arylane-H Dialyzer cleared under K982413, the Gambro Polyflux-S Dialyzer cleared under K982414, the Gambro HC 14R Hemoconcentrator cleared under K951311, and the Fresenius Hemoflow Dialyzer cleared under K926005. Reference to equivalence as outlined in this submission is in no way related to the term "equivalent" or similar terminology as outlined under the patent laws.
Clinical data:	N/A

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Conclusions drawn:	Components of the subject SYNTRA™ Dialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical Devices – Part: Guidance on selection of tests. Validation of the gamma sterilization cycle for the SYNTRA™ Dialyzer is based upon AAMI/ISO 11137-1994 "Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization." Pyrogen testing of the subject dialyzers meets the requirements of USP 24 (ref. 2) <161>, Transfusion and Infusion Assemblies and Similar Medical Devices. Particles are counted per USP XXIII Monograph <788>. This procedure is performed initially for information only and is not a release criteria at this time. Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release to ensure a quality product.
Additional information requested by FDA:	None to date.

Official Correspondent:

Robert L. Wilkinson — 7/20/00

Robert L. Wilkinson
Director, Regulatory Affairs

Date

Prepared by:

Robert L. Wilkinson — 7/20/00

Ann Marie Pahlman
Manager, Regulatory Affairs
FOR

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Robert L. Wilkinson, RAC
Director Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
MCGAW PARK IL 60085-6730

Re: K002210
SYNTRA™ 120 and 160 Hemodialyzers
Dated: January 15, 2001
Received: January 16, 2001
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Wilkinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

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510 (k) Number K002210

Device Name SYNTRA™ Dialyzer

Indications for Use Use Hemodialysis with SYNTRA™ is indicated for patients with renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002210